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मानक

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Mazdoor Kisan Shakti Sangathan

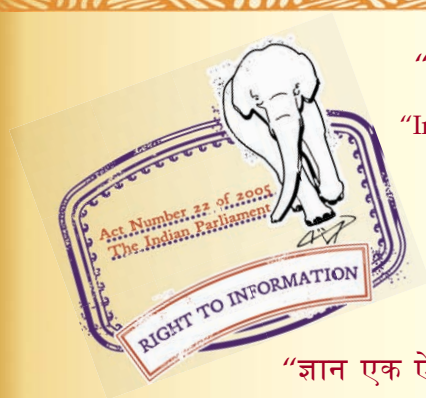
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Jawaharlal Nehru

“Step Out From the Old to the New”

IS 6436 (1989): Thoracic Surgery Instruments - Rib Spreader, Finochietto's Pattern, Adult Size [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

THORACIC SURGERY INSTRUMENTS — RIB
SPREADER, FINOCHIETTO'S PATTERN,
ADULT SIZE — SPECIFICATION

(First Revision)

भारतीय मानक

छाती संबन्धी शल्यक्रिया उपकरण — पसली स्प्रेडर, फिनोशिएटो नमूने का,
व्यस्क साइज — विशिष्ट

(पहला पुनरीक्षण)

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1971. In this revision, tolerances on various dimensions have been specified and the requirements for material, hardness, surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been included.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

Indian Standard

THORACIC SURGERY INSTRUMENTS — RIB SPREADER, FINOCHIETTO'S PATTERN, ADULT SIZE — SPECIFICATION

(*First Revision*)

1 SCOPE

This standard prescribes requirements for adult size, Finochietto's pattern rib spreader used in thoracic surgery.

2 REFERENCES

The Indian Standards listed below are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
IS 1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV5 to HV 100 (<i>second revision</i>)
IS 4905 : 1968	Methods for random sampling
IS 6603 : 1972	Specification for stainless steel bars and flats
IS 7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIAL

The materials of various components of the rib spreader shall be as given below:

<i>Components</i>	<i>Material</i>
Jaws	Stainless steel conforming to Designation 20Cr13 of IS 6603 : 1972
Rack, propelling stud and handle	Stainless steel conforming to Designation 30Cr13 of IS 6603 : 1972

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the rib spreader shall be as shown in Fig. 1.

4.2 With the movable jaw end flush with the end of the rack, the gap between the jaws shall be 160 mm

4.3 Tolerances

The tolerances on various dimensions shall be as specified below:

- ± 0.05 mm on dimensions up to 2.0 mm,
- ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm,
- ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm,
- ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm,
- ± 1.0 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- ± 2.0 mm on dimensions above 100.0 mm.

5 HEAT TREATMENT

The rack, propelling stud and jaws of the rib spreader shall be suitably heat treated. When tested in accordance with IS 1501 (Part 1) : 1984, the hardness of various components shall be as given below:

<i>Components</i>	<i>Hardness</i>
Jaws	380 to 420 HV
Rack, propelling stud and handle	420 to 470 HV

6 WORKMANSHIP

6.1 The movement at the rack shall be smooth and free from jerks.

6.2 With the movable jaw fixed at any position, there shall be no play at the rack.

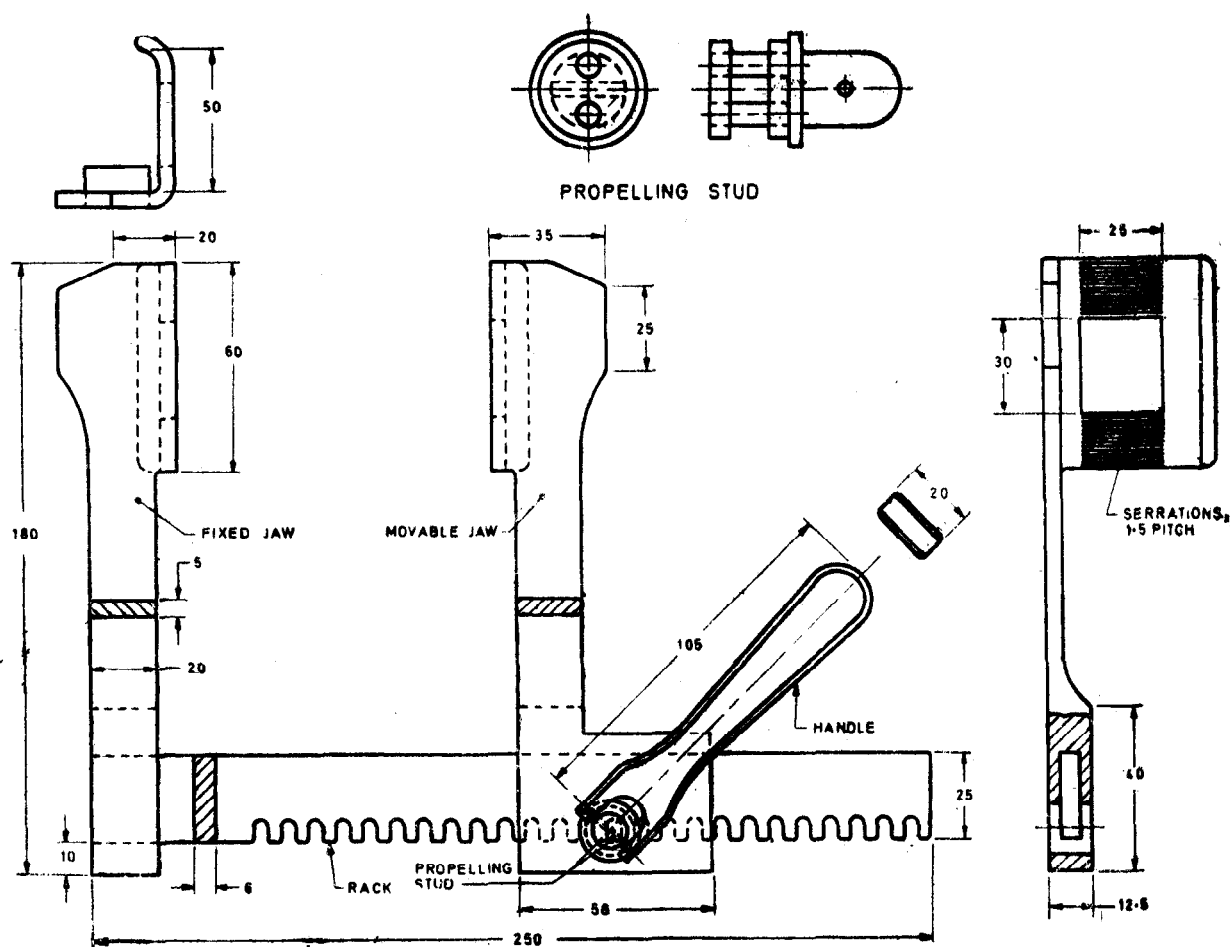
6.3 The faces of the jaws shall be true.

6.4 All edges and corners shall be rounded.

7 SURFACE CONDITION

7.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instrument shall be free



All dimensions in millimetres.

FIG. 1. SPREADER, RIB, FINOCHIETTO'S PATTERN, ADULT SIZE

from residual scales, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

7.2 Surface Finish

The surface finish shall be one of, or a combination of, the following:

- Mirror polished; and
- Reflection-reducing, for example, satin finish, matt black finish,

NOTES

1 The satin finish should be achieved by an appropriate procedure, such as, grinding, brushing electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be achieved by an appropriate procedure, such as, polishing, brushing, electropolishing and mirror buffing.

7.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C.

The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

8 TESTS

8.1 Performance Test

With the movable jaw fixed at five different positions along the rack, a force of 50 N (5 kgf approximately) shall be applied each time at the jaw ends, tending to bring the jaws together. The distance between the jaws shall remain unchanged on the application of the force.

8.2 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

9 MARKING AND PACKING

9.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'Stainless Steel' or letters 'SS'; and the country of manufacture.

9.2 Each instrument shall be put in a polyethylene bag or wrapped in wax paper. The instruments shall then be packed in cartons in accordance with the current trade practice.

9.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

9.3 The packages shall be marked with the name of the instrument, the manufacturer's name, initials or recognized trade-mark; the words 'Stainless Steel'; and the country of manufacture.

10 SAMPLING

The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(Clause 10)

SAMPLING OF RIB SPREADERS, FINOCHIETTO'S PATTERN

A-1 LOT

In any consignment, all the instruments produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 SCALE OF SAMPLING

The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling
(Clauses A-2, A-3.1 and A-3.2)

Lot Size	Sample Size	Sub-sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedure given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual). An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to A-3.1 shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to A-3.1. Each instrument in the sub-sample shall be subjected to hardness, performance and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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